Essai Clinique

Généré le 26 avr. 2024 à partir de

Titre	Étude de phase II multicentrique, ouverte et à répartition aléatoire, visant à évaluer l'asciminib oral en association avec l'imatinib, comparativement à la poursuite de l'imatinib et au passage à un traitement par le nilotinib chez des patients atteints de leucémie myéloïde chronique en phase chronique (LMC-PC), qui ont déjà reçu l'imatinib mais qui n'ont pas obtenu une réponse moléculaire profonde
Protocole ID	CABL001E2201
ClinicalTrials.gov ID	NCT03578367
Type(s) de cancer	Leucémie myéloïde chronique (LMC)
Phase	Phase II
Type étude	Traitement
Médicament	Asciminib + Imatinib vs Imatinib vs Nilotinib
Institution	CIUSSS DE L'EST-DE-L'ILE-DE-MONTREAL PAV. MAISONNEUVE/PAV. MARCEL-LAMOUREUX 5415 boul. de l'Assomption, Montréal, QC, H1T2M4
Ville	Montréal
Investigateur principal	Dr Lambert Busque
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Statut	Fermé
But étude	To evaluate efficacy, safety and pharmacokinetic profile of asciminib 40mg+imatinib or asciminib 60mg+imatinib versus continued imatinib and versus nilotinib in pre-treated patients with Chronic Myeloid Leukemia in chronic phase (CML-CP).
Critères d'éligibilité	• Male or female patients ≥ 18 years of age with a confirmed diagnosis of Chronic Myeloid Leukemia in chronic phase (CML-CP). • Minimum of two years (24 calendar months) treatment with imatinib first line for CML-CP (patients have to be on imatinib 400 mg QD at randomization and had no dose change in the past three months). • BCR-ABL1 levels > 0.01% IS (International Scale) and ≤ 1% IS at the time of study entry as confirmed with a central assessment at screening; patients must not have achieved deep molecular response (MR4 IS) at any time during prior imatinib treatment. • Patient must meet the following laboratory values before randomization: • Absolute Neutrophil Count ≥ 1.5 x 10E9/L • Platelets ≥ 75 x 10E9/L • Hemoglobin ≥ 9 g/dL • Serum creatinine < 1.5 mg/dL • Total bilirubin ≤ 1.5 x ULN (Upper Limit of Normal) except for patients with Gilbert's syndrome who may only be included with total bilirubin ≤ 3.0 x ULN • Aspartate transaminase (AST) ≤ 3.0 x ULN • Alanine transaminase (ALT) ≤ 3.0 x ULN • Alkaline phosphatase ≤ 2.5 x ULN • Patients must have the following laboratory values ≥ Lower Limit of Normal or corrected to within normal limits with supplements prior to randomization: potassium, magnesium, phosphorus, total calcium (corrected for serum albumin).

Critères d'exclusion	• Treatment failure according to European Leukemia Network (ELN) criteria 2013 during imatinib treatment. • Known second chronic phase of CML after previous progression to Accelerated Phase (AP)/Blast Crisis (BC). • Previous treatment with any tyrosine kinese inhibitors (TKIs) other than imatinib. • History or current diagnosis of ECG abnormalities indicating significant risk or safety for subjects participating in the study such as: • History of myocardial infarction, angina pectoris, coronary artery bypass graft within 6 months prior to randomization • Concomitant clinically significant arrhythmias • Resting QTcF ≥ 450 msec (male) or ≥ 460 msec (female) prior to randomization • Long QT syndrome, family history of idiopathic sudden death or congenital long QT syndrome, or any of the following: • Risk factors for Torsades de Pointes • Concomitant medications with a "known" risk of Torsades de Pointes • inability to determine the QTcF interval • Severe and/or uncontrolled concurrent medical disease that in the opinion of the investigator could cause unacceptable safety risks or compromise compliance with the protocol (e.g. uncontrolled diabetes, active or uncontrolled infection, uncontrolled clinically significant hyperlipidemia and high serum amylase) • History of acute pancreatitis within 1 year prior to randomization or past medical history of chronic pancreatitis. • History of other active malignancy within 3 years prior to randomization with the exception of basal cell skin cancer, indolent prostate cancer and carcinoma in situ treated curatively. • Other protocol defined inclusion/exclusion may apply.